DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
M Oleary

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

April 7, 1999

WARNING LETTER
CHI-15-99

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mrs. Shuk Fan Lum, President
Phoenix Bean Products, Inc.
5438 N. Broadway
Chicago, IL 60640

Dear Mrs. Lum:

On October 26, 27, 29 and November 2, 3, 4, and 17, 1998, the Food and Drug Administration (FDA) conducted an inspection of your bean processing plant. At the conclusion of the inspection you were presented with an Form FDA 483 listing deviations from FDA's Good Manufacturing Practice (GMP) regulations for foods, Title 21, Code of Federal Regulations (CFR), Part 110 (21 CFR 110). By virtue of these deficiencies, the products processed at your facility are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). During the inspection, labeling and information was also obtained to determine general compliance with FDA's labeling requirements for foods (21 CFR 101). Our review of labels reveals some products are misbranded within the meaning of Section 403 of the Act.

Specifically our investigators found:

- Evidence of an active rodent (rat) problem in the food processing and storage areas of the plant. For example, approximately [redacted] rat excreta pellets were observed in the bean sprout processing area;

- The presence of rodent access/harborage areas including holes in walls, openings around pipes, and storage practices (products against walls and unpalletized) making clean up and rodent detection and control difficult;

- Rodent traps located over and exposed to food in processing areas;

- Pooled water on floors in the food processing and food storage areas of the plant:

  Soy gelatin was being packaged in an area with standing water on the floor;
  Mung bean sprouts were in storage directly on the floor in standing water; and
  Floor drains were clogged.

- Employee practices, including:

  Finished product held in an outside alley unprotected while being cooled; and
  Food product being processed on top of garbage can.

- Structural defects, including:

  Holes in walls and around pipes as described in the second item above;
  Exhaust fumes from nearby road way entering through a street side vent into the processing area; and
  A hole in screening on the front entry door leading to packaging.

- Live and dead insects were observed on mung beans and tofu.

In addition, review of your product's labeling found some labels:

- Lacked nutritional labeling as required by 21 CFR Section 101.9, et al, i.e., Soy Bean Cake Soft Tofu, Soybean Gelatin Dessert, and Fresh Soybean Juice;

- Lacked an accurate ingredient listing in the ingredient statement (21 CFR Section 101.4), i.e., Glucono-delta-lactone is stated to be used in all tofu products but listed as an ingredient only on the Soy Bean Cake Soft Tofu label; and

- Salt and propylparaben as a preservative are listed on the Yellow Tofu label but stated not to have been used in the product for several years.

The investigators reported you have taken steps to correct some of the conditions. These included clean-up of debris and rodent droppings, repairs and clean-up to the toilet facilities, plastering of holes and painting of walls in the processing area, removal of overhead rodent traps in processing areas, addition of a ceiling fan, and cleaning of some equipment. We are also aware you obtained nutritional data for inclusion into your labeling and have instituted nutritional labeling on some of your products.

The above does not represent an all-inclusive listing of the violations noted during the inspection of your firm. It is your responsibility to assure adherence with each requirement of the GMP for foods and labeling requirements. You should make a critical evaluation of your sanitary practices and labeling to assure compliance. Failure to promptly correct these deviations may result in regulatory action without further notice. These include seizure and/or injunction.

Please notify this office in writing, within 15 working days after receipt of this letter, of the specific steps you have taken to correct the continuing violations. You should include an explanation of each step being taken to prevent recurrence.

Your reply should be directed to the attention of Paul Boehmer, Compliance Officer.

Sincerely,

/s/
Raymond V. Mlecko
District Director